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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/868,924 | 10/31/2001 | Shin-ichi Hashimoto | P21252 | 8540 |

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EXAMINER
MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/868,924 | Applicant(s) HASHIMOTO ET AL. | |
| | Examiner Irene Marx | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed 2/9/04 is acknowledged. Claims 1-9 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Deletion of “as is well known” and insertion of the limitation “in a culture broth” does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of strains having no ability to sporulate and showing no hyphal growth in a culture broth. The amendment raises issues of whether the strains have the ability to sporulate and showing no hyphal growth under solid phase growth, for example. There is not sufficient support for the new genus of microorganisms having the ability to sporulate and showing no hyphal growth “in a culture broth”. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of having the ability to sporulate and showing no hyphal growth “in a culture broth” is considered to be the insertion of new matter for the above reasons.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

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Issues of new matter are also raised by the replacement of ATCC 15098 with IFO 15098. Applicants indicate that this is a typographical error. However, there is no clear indication of how the alleged error occurred or the basis for the amendment in the as filed disclosure. That *Glomerula cingulata* is a fungus is not probative of error in this context, since the properties of fungi and *Actinomycetes* are specifically indicated to be at least similar in the instant written disclosure. See, e.g., the paragraph cited *supra*.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' presentation of suitable catalogue pages indicates that the strains are currently publicly available. However, the names and address of the depositories have not been inserted in the specification as required.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the requirement that the cultured microorganism "show no hyphal growth in a culture broth". This limitation is confusing and inconsistent with the written disclosure, since the genera, species and strains of microorganisms recited in dependent claims 6-9 would reasonably be expected show hyphal growth at least to some extent in any media. Thus, applicant specifically admits in the as filed specification that the invention is directed to the use of microorganisms having the ability to sporulate and grow in hyphal forms in at least some media, including, presumably, in a culture broth. That Bergey's Manual indicates that these strains do not *always* grow with filamentous forms by elongating hyphae does not address the claimed designation regarding "ability" in a culture broth as now

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amended. The issues of contamination and purification are not part of the invention as claimed, since process conditions are not part of the invention as claimed, and again, do not address “ability”. See also, the rejection under new matter *supra*.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kranjc *et al.* in light of the ATCC website. (www.ATCC.org), for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of hydroxylation using a microorganism that does not have the ability to sporulate and which shows no hyphal growth in culture broth, and in particular to the use of certain genera, species and strains of microorganisms.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' arguments are directed to differences between two specific strains, i.e., *Amycolatopsis orientalis* ATCC 19795 and *Rhodococcus rhodochrous* ATCC 21430. However, the claims are not directed only to ATCC 21430 and the differences between the reference strain

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and microorganisms “having no ability to sporulate and showing no hyphal growth in a culture broth” cannot be readily assessed, particularly in view of the inconsistencies and ambiguities in the instant record.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' the cultured strains used in the presently claimed process differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is an *Actinomyces* strain of at least a closely related genus and/or species as that claimed, likewise shares the property of being able to hydroxylate the compounds of interest, she has reasonably demonstrated a reasonable likelihood/possibility that the compared microorganisms are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Davis *et al.* in light of the ATCC website (www.ATCC.org) for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The claims are directed to a process of hydroxylation using a microorganism that does not have the ability to sporulate and which shows no hyphal growth in culture broth, and in particular to the use of certain genera, species and strains of microorganisms.

Applicants' arguments are directed to differences between two specific strains, i.e., *Pseudonocardia autotrophica* ATCC 35024 and *Rhodococcus rhodochrous* ATCC 21430. Applicants' statement that *Rhodococcus rhodochrous* ATCC 21430 has not been substantiated on this record. Moreover, the claims are not directed only to ATCC 21430 and the differences between the reference strain and microorganisms “having no ability to sporulate and showing no hyphal growth in a culture broth” cannot be readily assessed, particularly in view of the inconsistencies and ambiguities in the instant record.

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The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' the cultured strains used in the presently claimed process differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is an *Actinomycete* strain of at least a closely related genus and/or species as that claimed, likewise shares the property of being able to hydroxylate the compounds of interest, she has reasonably demonstrated a reasonable likelihood/possibility that the compared microorganisms are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Demain *et al.* U.S. Patent No. 5,942,423 in light of the ATCC website (www.ATCC.org) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of hydroxylation using a microorganism that does not have the ability to sporulate and which shows no hyphal growth in culture broth, and in particular to the use of certain genera, species and strains of microorganisms.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' arguments are directed to differences between two specific strains, i.e., particular strain of *Actinomadura* and *Rhodococcus rhodochrous* ATCC 21430. However, the claims are not directed only to ATCC 21430 and the differences between the reference strain and microorganisms "having no ability to sporulate and showing no hyphal growth in a culture broth" cannot be readily assessed, particularly in view of the inconsistencies and ambiguities in the instant record.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' the cultured strains used in the presently claimed process differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is an *Actinomycete* strain

of at least a closely related genus and/or species as that claimed, likewise shares the property of being able to hydroxylate the compounds of interest, she has reasonably demonstrated a reasonable likelihood/possibility that the compared microorganisms are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Okazaki *et al.* in light of the ATCC website. (www.ATCC.org.) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of hydroxylation using a microorganism that does not have the ability to sporulate and which shows no hyphal growth in culture broth, and in particular to the use of certain genera, species and strains of microorganisms.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' arguments are directed to differences between two specific strains, i.e., a particular strain of *Nocardia* and *Rhodococcus rhodochrous* ATCC 21430. However, the claims are not directed only to ATCC 21430 and the differences between the reference strain and microorganisms "having no ability to sporulate and showing no hyphal growth in a culture broth" cannot be readily assessed, particularly in view of the inconsistencies and ambiguities in the instant record.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' the cultured strains used in the presently claimed process differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is an *Actinomyce* strain of at least a closely related genus and/or species as that claimed, likewise shares the property of being able to hydroxylate the compounds of interest, she has reasonably demonstrated a reasonable likelihood/possibility that the compared microorganisms are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the

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burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 8 and 9 are allowable over the art of record there would have been no motivation for one of ordinary skill in the art to modify the processes of the prior art relating to hydroxylation processes in the manner claimed, by selecting the specific strains of microorganisms recited in claims 8 and 9.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651